

Chapter III 510(k) Summary

APR 10 2009

Blood Transfusion Set

As required by 21 CFR 807.92(k)

The assigned 510(k) Number is: K083349

1. Date Prepared: November 05, 2008;
2. Sponsor Information

ShanDong WeiGao Group Medical Polymer Co., Ltd
No.312 Shichang Road, Weihai City
Shangdong, 264209, China

Contact Person: Mrs. Zhao Suxia, Quality Manager
Tel: +86-631-5621632
Fax: +86-631-5620555
E-Mail: Zsx9001@sina.com

3. Submission Correspondent

Ms. Diana Hong
Mr. Lee Fu
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 8D, Zhongshan Zhongxin Mansion
No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, 200030, China

4. Device Name and Classification:

Device Trade Name: Blood Transfusion Set
Device Common Name: Blood Transfusion Set
Device Classification Name: Set, blood transfusion

K083349
242

Product Code: BRZ
Regulation Number: 880.5440
Device Class: II

5. Predicate Device Identification:
PENTATRASFU Blood Transfusion Sets
K-number: K041496

6. Intended Use:

Blood Transfusion Set is used to administer blood from a container (plastic bag or glass bottle) to a patient's vascular system through a needle or catheter inserted into a vein.

7. Device Description:

The proposed device is plastic, disposable and sterile blood transfusion set, which is intended to be used to administer the blood from the container to a patient's vascular system through a needle or catheter inserted into a vein via gravity method.

The blood transfusion set consists of protective cap of the closure-piercing device, closure piercing device, tubing, drip, flow regulator, transfusion needle and needle sheath. In addition, there are two kinds of the transfusion set, one has a drug-adding feature and the other hasn't.

There are two specifications of transfusion needle, which are 0.9# transfusion needle and 1.2# transfusion needle.

The proposed device is provided sterilized.

8. Test Conclusion

Laboratory testing was conducted to validate and verify that Blood Transfusion Set met all design specifications and was substantially equivalent to the predicate device.

9. Substantially Equivalent Conclusion:

The proposed device, Blood Transfusion Set, is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shan Dong Wei Gao Group Medical Polymer Products
C/o Ms. Diana Hong
General Manager
Shanghai Midlink Business Consulting Company Limited
Suite 8D, Zhongxin Zhongshan Mansion No. 19, Lane 999
Zhong Shan Nan Er Road
Shanghai, CHINA 200030

APR 10 2009

Re: K083349
Trade/Device Name: Blood Transfusion Set
Regulation Number: 21 CFR 880.5440
Regulatory Class: II
Product Code: BRZ
Dated: March 27, 2009
Received: March 31, 2009

Dear Ms. Hong:

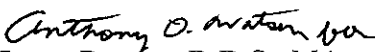
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number: K 083349

Device Name: Blood Transfusion Set

Indications for Use:

Blood Transfusion Set is used to administer blood from a container (plastic bag or glass bottle) to a patient's vascular system through a needle or catheter inserted into a vein.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083349